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Hemiplegia

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Literature Review

Treating Patients with Hemiplegic Shoulder Pain

ABSTRACT

Snels IAK, Dekker JHM, van der Lee JH, Lankhorst GJ, Beckerman H, Bouter LM: Treating patients with hemiplegic shoulder pain. *Am J Phys Med Rehabil* 2002;81:150–160.

Studies on the efficacy of available methods of treatment for hemiplegic shoulder pain are reviewed in an attempt to identify the most effective treatment for this problem. Because of the poor quality of the 14 selected studies, no definite conclusion can be drawn about the most effective method of treatment. However, functional electrical stimulation and intra-articular triamcinolone acetonide injections seem to be the most promising treatment options.

Key Words: Systematic Review, Stroke, Treatment, Hemiplegic Shoulder Pain

Shoulder pain is a common problem after stroke; the occurrence reported in the literature varies from 16 to 84%.^{1–8} Patients with hemiplegic shoulder pain remain hospitalized longer, and shoulder pain complicates the rehabilitation process.^{2,7} Physicians and therapists from many different disciplines are involved in the treatment of these patients, and many different methods of treatment have been described and applied to patients with hemiplegic shoulder pain.^{1,9} Many different measures have also been recommended to prevent hemiplegic shoulder pain.^{1–3,10–13}

In recent decades, several reviews on hemiplegic shoulder pain have been published.^{1,6,9,10,12,14} These reviews focus mainly on the etiology and treatment of hemiplegic shoulder pain. In general, the causes of hemiplegic shoulder pain can be divided into two categories: distant sources of (referred) shoulder pain (e.g., neck problems, visceral referred pain, thalamic pain) and local problems (e.g., rotator cuff disorders, adhesive capsulitis, subluxation of the glenohumeral joint, tendinitis, spasticity).^{1,6,9,12,14} Pain in the hemiplegic shoulder may also be caused by shoulder-hand syndrome or reflex sympathetic dystrophy.^{6,10,12,14} From the reviews that have been published, no conclusion could

be drawn about the most effective method of treatment for hemiplegic shoulder pain for the following reasons. First, because they were not systematic. Second, no attempt has been made to estimate the methodological quality of the published studies, and third, success rates were not always mentioned. Furthermore, since the most recent review¹² was published, several interesting intervention studies¹⁵⁻¹⁸ on hemiplegic shoulder pain have been published. In an attempt to identify the most effective method of treatment for hemiplegic shoulder pain, the literature was searched for studies that describe the results of an intervention to treat hemiplegic shoulder pain.

METHODS

A search was made in MEDLINE (from 1966 to October 1999), Embase (from 1988 to September 1998), CINAHL (from 1982 to September 1999), REHABDATA (from 1994 to July 1999), and the Cochrane Library (issue 2, 1999). The following keywords were used: (1) hemiparesis, hemiplegia, stroke, cerebrovascular disorder, cerebrovascular disease, brain injury, or brain ischemia; (2) shoulder, arm, or upper extremity; and (3) pain. For practical reasons, only studies published in Dutch, English, French, or German were selected. Further selection was based on the title and abstract. Only studies concerning the treatment of hemiplegic shoulder pain were included, and pain had to be one of the outcome measures. No restrictions were made with regard to study design. The references of the available articles were tracked for further possible studies.

The selected studies were rated for methodological quality independently by two reviewers (I. Snels and J. Dekker). One study was reviewed by the third author (J. van der Lee) because it was written by the second author. The review process was not

blinded. The criteria list used to assess the methodological quality of the selected studies is presented in Table 1. Similar criteria have been used in other reviews.¹⁹⁻²²

Although most studies described more than one outcome measure, only the scores for the outcome pain were taken into account in the calculation of the methodological score (item 13). The methodological score for each study was calculated by adding the points for each item together, the maximum possible score being 48 (100%). Thus, the higher the score, the higher the quality. A score of zero for an item meant that either the information about that item was not well described, or there was no information about it at all in the publication.

Data on study design, study population, and intervention were extracted. If possible, success rates for each treatment group were calculated as the percentage of patients treated successfully (according to the authors) divided by the total number of patients allocated to that specific treatment group (intention-to-treat).

RESULTS

Selected Studies

On the basis of both the title and abstract, 25 articles were identified. Of these, 11 articles were excluded for the following reasons: in one study, the intervention was diagnostic instead of therapeutic;²³ in two studies, the outcome measures did not include pain;^{24,25} three studies dealt with primary prevention;^{18,26,27} in two studies, the intervention was aimed at reducing spasticity instead of pain;^{28,29} and three studies dealt with reflex sympathetic dystrophy and shoulder-hand syndrome instead of hemiplegic shoulder pain.³⁰⁻³² Reference tracking resulted in one additional publication³³ that met the criteria; however, it referred to a

study by Caldwell et al.³⁴ that had already been selected, so the data of these two articles were combined.

Fourteen studies met the inclusion criteria and were rated for methodological quality.^{15-17,33-44} Before the consensus meeting, the reviewers disagreed on 64 out of 672 items (9.5%). Most disagreements between the reviewers resulted from reading errors and were easily resolved. The final methodological score was determined by consensus. Table 2 presents the study characteristics of the 14 studies, which are grouped according to the aim of the intervention: (1) normalization of muscle tone, (2) reduction of glenohumeral subluxation, and (3) treatment of the shoulder capsule. Within these three groups, the various studies are ranked in order of decreasing methodological score.

The methodological scores ranged from 2 to 25 of 48 (4-52% of the maximum score), indicating the overall poor methodological quality. Eight studies scored less than 10 points (21% of the maximum score), two of which were not even above the minimum score of 2 points. This minimum score of 2 points implies that only the type of intervention is mentioned (1 point) and that pain is an outcome measure that is clinically relevant (1 point). These factors were inherent to the inclusion criteria.

Table 2 shows that the success rates vary from 0 to 100%. It was not possible to calculate the success rate for the interventions described in four of the studies because the results were only reported at group level^{17,39} or because the number of patients who were treated successfully was not mentioned.^{41,43} As shown in Figure 1, success rates are inversely related to methodological quality. Only the success rates in the studies carried out by Williams⁴⁴ (52%), Chantraine et al.¹⁵ (67%) and Dekker et al.¹⁶ (46%) conform to an intention-to-treat analysis.

TABLE 1

Criteria list used to assess the methodologic quality of intervention studies on hemiplegic shoulder pain

Description of Items and Subitems	Maximum Score
Study population	
1 Selection of patients (at least two clear selection criteria are described)	1
2a Randomization or matching	1
2b Adequate description of the procedure	1
3 Comparability of the groups for the following prognostic variables: (a) time since onset stroke; (b) baseline scores for pain; (c) age; (d) first or repeated stroke; (e) neuropsychological problems (e.g., neglect) (f) type of stroke (infarction/hemorrhage, 1 point for each variable)	6
4a Drop-outs described (definite and temporary; 1 point for each possibility)	2
4b Reasons for drop-out described	1
4c No bias because of drop-outs	1
4d e Percentage of drop-outs in experimental group described	1
4d c Percentage of drop-outs in control group described	1
5a Follow-up described	1
5b Duration of follow-up described	1
5c Number of relapses described	1
6a Loss to follow-up for each treatment group described	1
6b Reasons for loss to follow-up described	1
6c No bias occurred because of loss to follow-up	1
6d e Percentage of loss to follow-up in experimental group described	1
6d c Percentage of loss to follow-up in control group described	1
Interventions	
7 In experimental group: (a) type of intervention; (b) intensity; (c) compliance described (1 point for each aspect)	3
8 In control group: (a) type of intervention; (b) intensity; (c) compliance described (1 point for each aspect)	3
9 Co-interventions in each group: (a) described; (b) similar in all groups (1 point for each item)	2
Blinding and outcome measurement	
10a Attempt to blind patients	1
10b Blinding successful	1
11a Attempt to blind therapist/physician	1
11b Blinding successful	1
12a Attempt to blind observer of effect	1
12b Blinding successful	1
13 Outcome measure ^a : (a) clinically relevant; (b) reliable; (c) valid (1 point for each aspect)	3
14 Similar timing of outcome measurements in all treatment groups	1
Data presentation and analysis	
15 Intention-to-treat analysis	1
16a Analysis between groups	1
16b Level of significance or confidence interval given	1
16c Correction for time-dependency for trends if necessary	1
17a Frequencies given	1
17b Mean and standard deviations given	1
17c Median given	1
Total	48

^aThe outcome measure of interest is pain.

Characteristics of Selected Studies

As can be seen in Table 2, the study designs of the selected studies are very divergent. There are three randomized clinical trials (RCTs),^{17,39,41}

one randomized trial with a crossover design,⁴⁴ one controlled study (not randomized),¹⁵ one multiple baseline design,¹⁶ five case series,^{33,34,38,40,42,43} and three case reports.³⁵⁻³⁷ Of the fourteen studies, two included more than

50 patients^{15,41} and five included less than 10 patients.^{16,35-37,42} Nine studies did not include a control group.^{16,35-38,40,42,43}

The characteristics of the study populations are also presented in

TABLE 2

Characteristics of intervention studies on hemiplegic shoulder pain

1st Author, Methodologic Score (MS) (%)	Study Design (n) and Study Population	Intervention	Co-intervention	Main Outcome Measures	Follow-up	Reported Results and Conclusions, Success Rate (SR) ^a
1. Interventions aimed at normalization of muscle tone						
Williams ⁴⁴ MS 25 (52)	Randomized crossover trial (n = 20) Hemiparesis or hemiplegia based on vascular disease; 3–16 wk. after stroke; HSP; no shoulder pain prior to stroke; no spasmolytic medication; informed consent	Group 1 (n = 10): EMG biofeedback for 30 min on 5 days Group 2 (n = 10): relaxation exercises for 30 min on 2 days; after 1 wk, subjects were reassigned to the opposite treatment group	Conventional PT for 1 hr, frequency not mentioned	Pain: Pain Rating Index and Present Pain Intensity scale of McGill Pain Questionnaire ROM: electrogoniometer	Group 1: 2 wk Group 2: 3 wk	Both groups: pain down, ROM up; between groups: no significant differences SR pain (after 2 wk) Group 1: 5/10 (50%); group 2: 6/10 (60%) SR ROM nc
Hecht ³⁸ MS 7 (15)	Cases series (n = 13) hemiplegia >3 mo and <2 yr based on CVA (11) or head injury (2); passive SLROM <50% of normal spasticity; pain in shoulder or upper arm at rest or in ROM; conventional treatment failed over last 2 wk; no other causes for pain, no allergy to alcohol, phenol, or local anesthetics	6.7% aqueous phenol solution in nervus subscapularis after local skin anesthesia with xylocaine	Sedation for head-injured patient with low threshold for discomfort	ROM: not mentioned (improvement in % of normal ROM) pain: comparison by therapist of clinical response (e.g., facial expressions, vocalizations, and patient subjective response)	None	ROM flex, abd and SLROM up (immediately after injection); pain down in all patients in the original arc of motion but was still present at new extremes Side effects: during the procedure some discomfort and, in one patient, generalized increase in shoulder soreness the day after the injection SR pain 13/13 (100%) ROM up, pain down SR pain 2/2 (100%) SR ROM 2/2 (100%)
Chironna ³⁵ MS 4 (8)	Case report (n = 2) hemiplegia based on cerebral infarction (one woman) or intracerebral hematoma and skull fracture (one man)	Phenol motor point block to subscapularis muscle	Not mentioned (woman), combination of US, antiinflammatory drugs and PT, motor point block to the pectoralis major muscle (man)	ROM: examination Pain: patient complaint (woman), examination? (man)	3 mo (woman); not mentioned (man)	
Partridge ⁴¹ MS 17 (35)	Multicenter RCT, (n = 85, 20 were withdrawn before completing the treatment)	Group 1: cryotherapy (ice towels applied to the shoulder for max 10 min, followed by exercises) Group 2: Bobath approach to the shoulder Both groups received treatment daily for the first 5 days, thereafter, only therapy if necessary Number of patients per group not mentioned	General PT (but not for shoulder during the intervention period), including advice and instruction about management and positioning of the shoulder	Pain in rest and on movement: severity 6-point scale, frequency of occurrence 5-point scale, affective response to pain 4-point scale ROM: mechanical device (normal, no movement or movement attempted but abnormal pattern compared with the non-involved side)	None	Both groups: pain down between groups no significant differences; only the frequency of occurrence of pain was less in the Bobath group SR pain nc SR ROM nc

TABLE 2
Continued

1st Author, Methodologic Score (MS) (%)	Study Design (n) and Study Population	Intervention	Co-intervention	Main Outcome Measures	Follow-Up	Reported Results and Conclusions, Success Rate (SR) ^{a,c}
2. Interventions aimed at reducing subluxation						
Chantraine ^{1,5} MS 23 (48)	Non-randomized controlled study (n = 120) One-sided HSP with subluxation; rehabilitation started between 2 and 4 wk after causal lesion (no tumor); no previous shoulder pain; no trauma of shoulder; no sympathetic dystrophy; informed consent	Exp group (n = 60): FES: in wk 1, 130 min in three sequences: first 90 min, 8 Hz; second 30 min, 40 Hz; third 10 min, 1 Hz; in wk 2-3 the first and third sequence lasted 5 min longer, and in wk 4-5, another 5 min longer Control group (n = 60): no additional FES	Conventional rehabilitation therapy according to the Bobath concept	Pain: recorded by physician (present or absent during active and passive motion), VAS, no pain = all these variables negative subluxation: x-rays	24 mo	Percentage of patients with no shoulder pain: control group: 36 at 3 mo, 47 at 6 mo, 55 at 12 and 24 mo FES group: 70 at 3 mo, 77 at 6 mo, 81 at 12 and 24 mo Percentage of subluxation improved ^b : control group: 40 at 6 mo, 59 at 12 and 24 mo, FES group: 74 at 6 mo, 79 at 12 and 24 mo SR pair ^{a,c} : control group: 21/60 (35%) at 3 mo, 27/60 (45%) at 6 mo, 32/60 (53%) at 12 and 24 mo FES group: 40/60 (67%) at 3 mo, 44/60 (73%) at 6 mo, 46/60 (77%) at 12 and 24 mo SR subluxation ^{a,c} : control group: 23/60 (38%) at 6 mo, 34/60 (57%) at 12 and 24 mo FES group: after 6 wk, mean arm function, tone, and EMG activity was up, after 12 wk, no significant differences between the groups SLROM: average difference between involved and uninvolved limb was higher for the controls (indicating pain increase for controls); SR ROM nc
Faghri ¹⁷ MS 16 (33)	RCT (n = 26) Recent stroke; shoulder muscles flaccidity; no pacemaker	Exp group (n = 13): FES duration and intensity progressively increased to 6 h/d, 6 wk; control group (n = 13): no additional FES	Conventional, PT for both groups	Arm function: modified Bobath assessment chart pain: SLROM (goniometer) arm function recovery: surface EMG of deltoides posterior muscle subluxation: x-ray spasticity: modified Gross clinical scales	6 wk	

TABLE 2
Continued

1st Author, Methodologic Score (MS) (%)	Study Design (n) and Study Population	Intervention	Co-intervention	Main Outcome Measures	Follow-Up	Reported Results and Conclusions, Success Rate (SR) ^a
Caldwell ³⁴ Braun ³³ MS 8 (17)	Case series (n = 25) Stroke patients with HSP and spasticity; regular therapy failed; marked restriction of SLROM and abd	Exp group (n = 13): surgical release of subscapularis tendon and of the insertion of pectoralis major muscle Control group (n = 12): no surgery	Exercise program started on the second postoperative day and an abduction brace and suspension sling	ROM: not mentioned Pain: patients' complaints	Exp group: 2 mo Control group: 6 mo	Exp group: after operation 10 patients no longer complained of shoulder pain, use of upper extremity increased, participation in rehabilitation program increased; 3 patients had no improvement Control group: six patients became one-handed, six continued exercising and were operated on later No spontaneous resolution of the symptomatic contracture SR pain 10/13 (77%) (exp), not mentioned for controls
Pinzur ⁴² MS 7 (15)	Case series (n = 6) Hemiplegia based on CVA (4), brain injury (1), aneurysm (1), painful inferior subluxation, slings were not successful	Surgery	Lifelong sling after operation	Subluxation: X-rays Pain: subjective patient's satisfaction	10–39 mo (mean 27.2 mo)	Subluxation in all cases resolved, five patients no longer had pain, one patient no change in pain SR pain 5/6 (83%)
Gruskin ³⁷ MS 6 (13)	Case report (n = 1) left hemiplegia after CVA	Auditory feedback device	Intensive program of PT and OT	Pain: patient's complaints	None	SR subluxation 6/6 (100%) After 2 wk use of the device, the patient no longer complained about shoulder pain
Rajaram ⁴³ MS 3 (6)	Case series (n = 20) stroke; painful, flaccid upper extremity	Sling consisting of a shoulder and a forearm support	Not mentioned	Subluxation: X-rays Pain: patient's report	Not mentioned	SR pain 1/1 (100%) 90% success, unclear how success was defined SR pain nc SR subluxation nc
Krempen ⁴⁰ MS 2 (4)	Case series (n = 21) Stroke or upper motor neuron lesions, painful subluxated shoulder	Varney brace	Active exercise program	Subluxation: not mentioned Pain: not mentioned	Not mentioned	Most often after 5–7 days symptoms decreased; in 2 patients pain persisted 2 wk SR pain 21/21 (100%) (after 2 wk) SR subluxation not mentioned

TABLE 2
Continued

1st Author, Methodologic Score (MS) (%)	Study Design (n) and Study Population	Intervention	Co-intervention	Main Outcome Measures	Follow-Up	Reported Results and Conclusions, Success Rate (SR) ^a
Egan ³⁶ MS 2 (4)	Case report (n = 1)	"Splint jacket"	Not mentioned	Pain: not mentioned	Not mentioned	After the jacket had been worn for some time, pain subsided SR pain 1/1 (100%)
3. Treatments aimed at treatment of the shoulder capsule						
Dekker ¹⁶ MS 22 (46)	Multiple baseline (n = 9) Cerebral infarction; HSP with sleep disturbance; no earlier shoulder problems; SLROM decreased; no change in medication	Three i.a. triamcinolone acetate injections, 40 mg/ml, on days 1, 8, 22 (seven patients treated, two dropped out before treatment)	Regular rehabilitation program, no therapies on the day of injection	Pain: VAS SLROM: goniometer Spasticity: Ashworth scale Arm function: FM, ARA Side effects	7–12 d	Five patients: pain down, 4 ROM up Five patients: side effects: flaring SR pain ^a 5/9 (56%) SR SLROM ^a 4/9 (44%)
Inaba ³⁹ MS 18 (38)	RCT (n = 33) Hemiplegia; shoulder pain in ROM flex or abd 0–90 degrees	Control group (n = 13): self ROM exercises three times per day and arm positioning during 4 wk, exp group (n = 10): at least 15 times US (0.5–2 W/cm ²) prior to the exercises; placebo group (n = 10): same as exp group with US turned off	Not mentioned	ROM: goniometer Pain: protective reactions and complaints	None	No difference in the three groups before and after 4 wk of treatment; insufficient data to analyze change in pain SR ROM nc SR pain nc

MS, methodologic score; SR, success rate; HSP, hemiplegic shoulder pain; EMG, electromyography; PT, physiotherapy; ROM, range of motion; nc, not computable; CVA, cerebrovascular accident; SLROM, shoulder lateral range of motion; flex, flexion of the shoulder; abd, abduction of the shoulder; RCT, randomized clinical trial; exp, experimental; FES, functional electrical stimulation; VAS, visual analogue scale; OT, occupational therapy; i.a., intra-articular; FM, Fugl Meyer; ARA, Action Research Arm test.

^a SR according intention-to-treat.

^b Improvement is normal position or grade 1 on Bats scale.

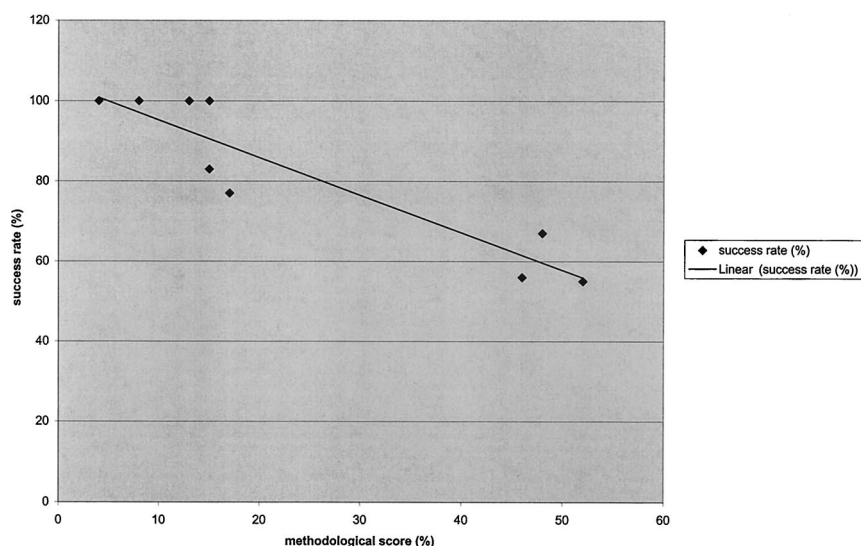


Figure 1: Success rate in relation to methodological score of 10 studies. Only the success rates of Williams⁴⁴ (52%), Chantraine et al.¹⁵ (67%), and Dekker et al.¹⁶ (46%) are according to intention-to-treat analysis.

Table 2. Many studies investigated hemiplegic shoulder pain in patients with subacute and chronic stroke.

Interventions

The interventions studied were electromyographic (EMG) biofeedback,⁴⁴ functional electrical stimulation (FES),^{15,17} intra-articular triamcinolone acetate injections,¹⁶ ultrasound,³⁹ cryotherapy,⁴¹ surgery,^{33,34,42} phenolization,^{35,38} auditory feedback,³⁷ sling,⁴³ brace,⁴⁰ and splint jacket.³⁶ In general, these interventions were quite adequately described (Table 2). The co-interventions were either described in general terms only^{15–17,34,35,37,38,40–42,44} or not mentioned at all.^{36,39,43} The follow-up period varied from 0 to 39 mo. In four studies, the follow-up period was not specified.^{35,36,40,43}

Outcome Assessment

Pain was the outcome of interest in the present review. To estimate the effect of an intervention on pain, it must be clear how the pain was assessed. Williams⁴⁴ used the validated McGill Pain Questionnaire, and Dekker et al.¹⁶ used a visual analog scale, which has also been validated. Chan-

traine et al.¹⁵ also used a visual analog scale, but they combined this scale with other pain measures that were not well described, and no results were reported for the separate pain measures. Partridge et al.⁴¹ used several 4–6 point scales, but they provided no information about the clinical properties. Hecht³⁸ described which patient reactions were used to rate the pain. This method seems, at least, to have some face validity. The range of motion does not seem to be a valid instrument with which to measure pain.¹⁷ In the other studies, pain was assessed directly from the reactions of the patients,^{33,34,36,37,39,42,43} on the basis of a therapist's interpretation of the reactions of the patients,³⁸ or there was no description of how the pain was assessed.³⁵

Results of the Interventions

Interventions Aimed at Normalization of Muscle Tone. The randomized crossover trial investigating the effect of EMG biofeedback combined with relaxation exercises attained the highest methodological score and had a success rate after 2 wk of 50–60%.⁴⁴ Because both methods of treatment are applied without a wash-out period, it is impossible to

calculate the success rate for each separate treatment. The follow-up period was also different for the two groups. Another method which is used to reduce spasticity is phenolization. This treatment was applied in two studies, with a success rate of 83% in a case series study³⁸ and 100% in a case report study.³⁵ Cryotherapy is a third method that is applied to reduce pain and spasticity.⁴⁵ Partridge et al.⁴¹ found no beneficial effects of cryotherapy compared with the Bobath approach to the hemiplegic shoulder.

Interventions Aimed at Reducing Subluxation. In a controlled non-randomized trial,¹⁵ compared with patients in a control group who received no (additional) FES therapy, more patients with FES were without pain at 3 and 24 mo posttreatment: 36% vs. 70% and 55% vs. 81%, respectively. In an RCT, no significant effect of FES was found at 12 wk.¹⁷

Surgery was used to reduce subluxation, with success rates of 77–83%.^{33,34,42} The surgery was followed by exercises and a sling. Other methods applied in studies to reduce subluxation were a Varney brace,⁴⁰ sling,⁴³ auditory feedback³⁷ and a splint jacket.³⁶ All of these methods resulted in success rates of 90–100%. The methodological score of all studies investigating the effect of surgery or shoulder supports was below 10 points (21%).

Interventions Aimed at Treatment of the Shoulder Capsule. A third category of possible treatments for hemiplegic shoulder pain focuses on the shoulder capsule. The effect of intra-articular triamcinolone acetate injections (as a cause for hemiplegic shoulder pain) was investigated in one study.¹⁶ The success rate of this treatment was 56%. Contractures of the shoulder resulting from capsular tightness can also be treated with ultrasound.³⁹ No effect was found for a 4-wk period

of ultrasound treatment with regard to range of motion in the shoulder. Direct assessment of pain (protective reactions and complaints of patients) yielded insufficient data for analysis of the change in pain. Indirect assessment of pain (range of motion) showed no differences between the intervention and the control groups.³⁹

DISCUSSION

Fourteen studies were identified during the literature search, and it seems unlikely that any important publication was missed during this thorough search. However, it is possible that relevant studies remained unpublished or have been published in journals that are difficult to retrieve. The design of the selected studies was very divergent and ranged from case reports^{36,37} to RCTs.^{17,39,41} RCTs provide the most convincing results with regard to the evaluation of interventions.^{46,47} Case reports, on the other hand, are not considered to be convincing at all. To make it possible to compare the methodological quality of studies with such diverse designs, a very detailed criteria list was used. Although it is difficult to attain the maximum score of 48 points, it was disappointing that the study with the best methodological quality only scored 25 points (52%). Eight studies scored less than 10 points, two of which were not even above the minimum score of 2 points. Thus, the methodological quality of the selected studies was found to be poor. In many cases, there was insufficient or inadequate information about the study population; the duration of the shoulder pain; the exact intervention; blinding of the patient, therapist, and the observer of the effect; dropouts; follow-up; co-interventions; and statistical methods. This could have been the result of poor reporting, but it probably indicates real shortcomings in study design and execution.

Surprisingly, the three studies with the highest methodological score^{15,16,44} were not the three RCTs.^{17,39,41} The reason for this is probably that no weight factors were assigned to the items on the detailed criteria list. Therefore random treatment allocation and masked outcome assessment were relatively underscored.

Adequately concealed treatment allocation and masked outcome assessment have been shown to decrease the estimate of the treatment effect in meta-analyses of RCTs,^{48–50} including low-quality RCTs in meta-analyses, which increase the overall estimate of the treatment effect by 30–50%.^{49,50} The three RCTs^{17,39,41} had major methodological shortcomings, and it is therefore possible that the success rates found in these studies are overestimated.

The review process was not blinded. From meta-analyses of RCTs, it is known that masked assessments, compared with unmasked assessments, of the methodological quality of studies sometimes result in different scores.^{49,51} However, Verhaegen et al.⁵² showed in their study that there was little difference between blinded assessment and unblinded assessment, and masking assessment did not change the overall conclusion of a meta-analysis of five RCTs.⁵³

Evaluation of the Interventions

Interventions Aimed at Normalization Muscle Tone. Several methods for reducing spasticity were investigated. The study combining EMG biofeedback and relaxation exercises had the best methodological score.⁴⁴ However, both methods of treatment are applied without a wash-out period, so it is impossible to draw separate conclusions about the individual effects of EMG biofeedback and relaxation exercises. The combination seems to be successful, regardless of the order in which these treatments are applied. However, the

question of whether these methods of treatment are better than no treatment at all, or placebo EMG biofeedback, remains unanswered. Moreover, the follow-up period was very short and was not the same for both groups.⁴⁴ In our opinion, the author's conclusion, that there is a trend that EMG biofeedback reduces pain, is not supported by the results presented in her publication.

The RCT on the effect of cryotherapy *vs.* the Bobath approach remains inconclusive because, according to the authors' references, cryotherapy should be applied to reduce pain and spasticity, but 22 patients out of the 65 who completed the treatment suffered from flaccidity, and six patients had normal tone. Moreover, 20 patients dropped out before the end of the treatment period.

The effect of phenol is described in two studies that were of poor methodological quality, so no conclusions can be drawn about its effectiveness.^{35,38} Botulinum toxin²⁸ and a wrapping technique are other methods of treatment that are applied to reduce spasticity,²⁹ but these studies were excluded from our review.

Interventions Aimed at Reducing Subluxation. FES was investigated in two studies. In both studies, the control group received no (additional) FES therapy.^{15,17} In the non-randomized controlled study, more patients in the intervention group than in the control group were without pain at 3 and 24 mo posttreatment.¹⁵ In the RCT, after 12 wk no differences were found between the groups.¹⁷ Because the control groups received no sham FES, it is possible that the effects of FES are simply nonspecific.

Other techniques used to reduce subluxation are surgery,^{33,34,42} Varney brace,⁴⁰ sling,⁴³ auditory feedback,³⁷ and a splint jacket.³⁶ No conclusions about the effectiveness of any of these techniques can be drawn because of the poor methodological

quality of the relevant studies. According to Hurd et al.,²⁶ hemiplegic shoulder pain cannot be prevented by a sling. Although a considerable amount of effort is being invested in finding a relationship between subluxation of the hemiplegic shoulder and shoulder pain, no such relationship has yet been found.⁵⁴

Interventions Aimed at Treatment of the Shoulder Capsule. Corticosteroid injections have been shown to be effective in the treatment of capsulitis of the shoulder.^{21,55,56} The signs and symptoms of hemiplegic shoulder pain are similar to those found in a nonhemiplegic painful shoulder (capsulitis adhaesiva).⁵⁷ Triamcinolone acetone injections seem to be a promising intervention for hemiplegic shoulder pain.¹⁶

Ultrasound is thought to reveal pain from joint contractures resulting from capsular tightness, scarring, and sprains in a nonhemiplegic shoulder. In an RCT, no effect of ultrasound on hemiplegic shoulder pain was found.³⁹ Vasodilatation induced by transcutaneous electrical nerve stimulation is reported to reduce myofascial pain, such as hemiplegic shoulder pain.²⁴

CONCLUSIONS

Although the success rates seem impressive (up to 100%), the methodological quality of the reviewed studies was moderate to poor. It is therefore concluded that none of the results are convincing enough to provide an answer to the question of which treatment is most effective for patients with hemiplegic shoulder pain. Further research is needed not only to find the best methods to prevent hemiplegic shoulder pain but also to find the most effective treatment for this problem. This research should be directed toward preventive measures and methods of treatment that are the least aggressive and seem to be biologically plausible and the

most promising (on the basis of present knowledge). All research should be based on high methodological standards, and therefore, RCTs are recommended. The authors suggest that the most promising methods of treatment for further research at this stage are FES and intra-articular triamcinolone acetone injections. Phenol injections seem to be biologically plausible for the treatment of muscle hypertonia.

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